

## Message Text

UNCLASSIFIED

PAGE 01 PARIS 22768 060057Z  
ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-07 EB-08 COME-00 /034 W  
-----129172 061820Z /50

R 051559Z AUG 77  
FM AMEMBASSY PARIS  
TO SECSTATE WASHDC 6724

UNCLAS PARIS 22768

E.O. 11652: N/A  
TAGS: OGEN, ETRD, EIND, TBIO, FR  
SUBJECT: FDA ADVISORY - PACER LEAD MALFUNCTION (RECALL  
T-129-7).

REF: STATE 4513.

1. MR. CHEVALIER, COMMERCIAL MANAGER, AHS FRANCE, 18  
RUE PAUL PAINLEVE - 95004 ST OUEN L'AUMONE, FRANCE,  
WHICH DISTRIBUTES PACEMAKERS MANUFACTURED BY  
EDWARDS PACEMAKER SYSTEMS, 1323 S.E. MAIN STREET, IRVINE,  
CA. 92713 WAS CONTACTED BY POST CONCERNING SUBJECT  
RECALL.

2. MR. CHEVALIER STATED THAT RECALL LETTERS HAD BEEN  
RECEIVED AND ENCLOSED INSTRUCTIONS HAD BEEN FORWARDED  
TO USERS OF DEVICE.

3. NO INCIDENTS OR MALFUNCTIONS HAD BEEN REPORTED.  
HARTMAN

UNCLASSIFIED

NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01-Jan-1994 12:00:00 am  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Sent Date:** 05-Aug-1977 12:00:00 am  
**Decaption Date:** 01-Jan-1960 12:00:00 am  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01-Jan-1960 12:00:00 am  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1977PARIS22768  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** n/a  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D770283-0281  
**Format:** TEL  
**From:** PARIS  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1977/newtext/t19770890/aaaacyhe.tel  
**Line Count:** 42  
**Litigation Code IDs:**  
**Litigation Codes:**  
**Litigation History:**  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Message ID:** b751e360-c288-dd11-92da-001cc4696bcc  
**Office:** ACTION HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 1  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** 77 STATE 4513  
**Retention:** 0  
**Review Action:** RELEASED, APPROVED  
**Review Content Flags:**  
**Review Date:** 19-Oct-2004 12:00:00 am  
**Review Event:**  
**Review Exemptions:** n/a  
**Review Media Identifier:**  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 1691070  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY - PACER LEAD MALFUNCTION (RECALL T-129-7).  
**TAGS:** OGEN, ETRD, EIND, TBIO, FR, US, AHS FRANCE, EDWARDS PACEMAKER SYSTEMS  
**To:** STATE  
**Type:** TE  
**vdkgvwkey:** odbc://SAS/SAS.dbo.SAS\_Docs/b751e360-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
22 May 2009  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009